



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-582/S-022

F. H. Faulding and Co.
c/o Warner Chilcott Inc.
Attention: Deepa Desai
Manager, Regulatory Affairs
Rockaway 80 Corporate Center
100 Enterprise Dr., Suite 280
Rockaway, NJ 07866

Dear Ms. Desai:

Please refer to your supplemental new drug application dated September 19, 2003, received September 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Doryx[®] (coated doxycycline hyclate pellets).

We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated October 24, 2003, and January 5, 2004.

This "Changes Being Effected" supplemental new drug application provides revisions to the package insert to comply with the Federal Notice of February 6, 2003, titled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use."

We have completed the review of this supplemental new application as amended, and it is approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted January 5, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and

**This is a representation of an electronic record that was signed electronically and
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/s/

Janice Soreth

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